REMARKS

In the Office Action, claims 1-72 are rejected under 35 U.S.C. § 112, second paragraph; claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57 are rejected under 35 U.S.C. § 102 or, in the alternative, under 35 U.S.C. § 103; and claims 1-72 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections are improper and thus should be withdrawn based on at least the reasons set forth below.

In the Office Action, claims 1-72 are rejected under 35 U.S.C. § 112, second paragraph. The Patent Office alleges that the claimed subject matter is vague in scope and meaning based on Applicants' purported assertions made in Applicants' previously filed response on October 15, 2003 (i.e., Remarks, Paper No. 10/20/2003). See, Office Action, page 2. Applicants believe that this rejection is improper.

At the outset, Applicants believe that the subject matter as defined in the claims is clear in scope and meaning as further supported in the specification as described below. Of the pending claims, claims 1, 17, 30, 44, 55 and 64 are the sole independent claims. Claim 1 recites a two part dialysis solution that includes a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and the second component include a physiological acceptable amount of sodium. Claim 4 depends from claim 1 and further defines that the bicarbonate concentrate and the electrolyte concentrate contain a physiological acceptable amount of potassium that ranges from about 0.1 mmol/L to about 5 mmol/L. Claim 5 depends from claim 1 and further defines that the first component does not include potassium and the second component includes potassium. Claims 2, 3 and 6-16 each depend from claim 1, directly or indirectly, and thus as a matter of law incorporate the features of claim 1. The subject matter as defined in claims 1-16 is fully supported in the specification. See, for example, Specification, p. 3, lines 9-20.

Claim 17 recites a two part dialysis solution that is designed to be infused into a patient. The solution includes a first component that includes a bicarbonate concentrate not including potassium and a second component including an electrolyte concentrate that includes potassium wherein the first component and the second component are so constructed and arranged that the second component physically cannot be infused into the patient without mixing with the first component. Claims 18-29 depend from claim 17, directly or indirectly, and thus incorporate the

features of claim 17 as a matter of law. The subject matter as defined in claims 17-29 is fully supported in the specification. See, Specification, for example, p. 3, line 9 to p. 4, line 6.

Claim 30 recites a two part dialysis solution that includes a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and the second component include a physiological acceptable amount of potassium. Claims 31-43 depend from claim 30, directly or indirectly, and thus incorporate the features of claim 30 as a matter of law. The subject matter as defined in claims 30-43 is fully supported in the specification. See, Specification, for example, p. 3, lines 9-20.

Claim 44 recites a method of providing hemofiltration to a patient. The method includes providing a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and the second component include a physiological acceptable amount of sodium; mixing the first component and the second component to form a mixed solution; and using the mixed solution during hemofiltration. Claims 45-54, directly or indirectly, depend from claim 44 and thus incorporate the features of claim 44 as a mater of law. The subject matter as defined in claims 44-54 is fully supported in the specification. See, Specification, for example, p. 3, line 9 to p. 4, line 10.

Claim 55 recites a method of providing hemofiltration to a patient. The method includes providing a first component including a bicarbonate concentrate that does not include potassium and a second component including an electrolyte concentrate that includes potassium; orienting the first component and the second component so that the second component physically cannot be infused into the patient without mixing with the first component; mixing the first component and the second component to form a mixed solution; and infusing the mixed solution into the patient. Claims 56-63, directly or indirectly, depend from claim 55 and thus as a matter of law incorporate the features of claim 55. The claimed subject matter as defined in claims 55-63 is fully supported in the specification. See, for example, p. 3, line 9 to p. 4, line 10.

Claim 64 recites a method of providing hemofiltration to a patient. The method includes providing a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and second component include a physiological acceptable amount of potassium; mixing the first component and the second component to form a mixed solution; and using the mixed solution during hemofiltration. Claims 65-72, directly or indirectly, depend from claim 64 and thus as a matter of law incorporate the features of claim 64. The subject matter as defined by claims 64-72 is fully

supported in the specification. See, Specification, for example, p. 3, line 9 to p. 4, line 10. Therefore, Applicants believe that one skilled in the art would understand the scope and meaning of the claimed subject matter in view of the claim language as further supported in the specification.

Further, Applicants' purported assertions made in the previously filed response as discussed above do not render the scope of the claimed subject matter indefinite contrary to the Patent Office's position. Indeed, each of the independent claims were recited and separately discussed in response to the prior art rejections on pages 2 and 3, for example, of Applicants' previously submitted response. Moreover, Applicants identified claims 17, 30, 55 and 64 as at least including potassium in the electrolyte concentrate where claims 30 and 64 recite, in part, potassium in each component part as provided on page 4 of Applicants' previously submitted response.

Based on at least these reasons, Applicants believe that one skilled in the art would readily understand the meaning and scope as separately and differently defined in each of independent claims 1, 17, 30, 44, 55 and 64 and dependents thereof. Therefore, Applicants believe that the claimed subject matter, as defined by claims 1-72, complies with 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57 are rejected under 35 U.S.C. § 102 as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,122,516 ("Watanabe"). Applicants believe that the anticipation or obviousness rejection in view of Watanabe is improper.

At the outset, clearly the anticipation rejection or, in the alternative, the obviousness rejection based solely on Watanabe is improper. Indeed, the Patent Office further relies on two additional references in combination with Watanabe to reject the same claims in a subsequent obvious rejection. See, Office Action, pages 3-6. Clearly, this suggests that Watanabe, on its own, is deficient with respect to the claimed invention as defined in claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57. Therefore, the anticipation and obviousness rejections based solely on Watanabe should be withdrawn for at least these reasons.

Further, Watanabe is clearly distinguishable over the claimed invention as defined in claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57. Of these claims, claims 1, 17, 44 and 55 are the sole independent claims and thus the remaining claims at issue depend from a

respective independent claim. As previously discussed, claim 1 recites a two part dialysis solution; claim 17 recites a two part dialysis solution that is designed to be infused into a patient; claim 44 recites a method of providing hemofiltration to a patient; and claim 55 recites a method of providing hemofiltration to a patient.

In contrast, the Watanabe reference on its own is clearly deficient with respect to the claimed invention. For example, the primary focus of Watanabe relates to a uniform, powdery preparation for blood dialysis. See, Watanabe, column 1, lines 9-11. Watanabe further discloses that the preparation can include a first powdery composition that includes solid electrolytes and a second powdery composition that includes sodium hydrogen carbonate and glucose. See, Watanabe, column 2, lines 41-46. In contrast, the claimed invention relates to bicarbonate containing solutions that include at least two separate solution components, such as a bicarbonate concentrate and an electrolyte concentrate, as required by independent claims 1, 17, 44 and 55. As further supported in the specification, the solution components can be readily, sterilely and effectively mixed to form a ready-to-use formulation. See, Specification, page 3, lines 3-8. The ready-to-use bicarbonate-based formulations as claimed can decrease the amount of time and effort with respect to the preparation and administration of such formulations as compared to conventional bicarbonate formulations. The ready-to-use formulations can also effectively eliminate, or at least greatly minimize, the potential of the spread of biological contamination during the preparation, administration and/or general use thereof. Such attributes of the bicarbonate-based formulations as claimed are desirable as applied to medical therapies, particularly in an intensive care setting. See, Specification, page 7, lines 13-20.

Further, Watanabe provides mere optional ingredients, such as potassium and sodium, in contrast to the solutions as claimed. For example, Watanabe discloses potassium as an optional ingredient as disclosed, for example, in column 2 at line 61. This clearly contrasts the subject matter as defined, for example, in claims 5, 17 and 55. Each of these claims recites, in part, that the electrolyte concentrate includes potassium. The claimed solution components can then be readily and sterilely mixed to form a ready-to-use solution for effective use. Moreover, this can provide an added safety feature where the potassium cannot be placed in direct fluid communication with a patient without mixing with the other components of the solution as further supported in the specification, for example, on page 11, at lines 7-19.

With respect to sodium content, the Watanabe reference is, at a minimum, deficient with respect to sodium at equimolar levels in both the electrolyte and bicarbonate concentrates in

contrast to claims 2, 3, 19, 45, 46 and 57. For example, the Watanabe reference provides that the sodium content ranges from 90 to 140 mmols in the first composition (electrolyte) and ranges from 15 to 40 mmols in the second composition (bicarbonate) as disclosed in columns 2 and 3, for example, of Watanabe. Moreover, the sodium content associated with the second composition (bicarbonate) as provided therein clearly falls outside of the claimed sodium range. Indeed, Watanabe discloses sodium in an amount, such as 15 to 40 mmole as discussed above, that is lower than the sodium concentration in the bicarbonate concentrate as claimed in claims 2, 3, 19, 45, 46 and 57.

The Watanabe reference also fails to place any mixing constraints on how the composition is prepared, let alone how it is administered during use. This clearly contrasts the subject matter as defined, for example, in claims 17 and 55. Indeed, claim 17 recites, in part, that the first component and the second component are so constructed and arranged that the second component physically cannot be infused into the patient without mixing with the first component; and claim 55 recites, in part, that the first component and second component are oriented so that the second component physically cannot be infused into the patient without mixing with the first component. This promotes the safe and effective use of the bicarbonate-based solutions as claimed and further supported in the specification, for example, on page 11 at lines 20-31.

Further, the Watanabe reference merely provides a general disclosure with respect to the use of the preparation for blood dialysis. Nowhere does Watanabe provide the use of its preparation with respect to continuous renal replacement therapy ("CRRT"), such as hemofiltration. For example, nowhere does Watanabe provide that its preparation can be used as a substitution, replacement or infusion fluid during CRRT that is infused into the patient. Thus, the emphasis of Watanabe relates to more traditional dialysis therapies, particularly hemodialysis, in contrast to the subject matter as defined, for example, in claims 16, 17, 44 and 55 that relates to hemofiltration. Indeed, the Patent Office relies an additional references for their purported teachings regarding same in support of the subsequent obviousness rejection. See, Office Action, pages 3 and 4.

Based on at least these reasons, Applicants believe that the Watanabe reference, on its own, is clearly distinguishable from the claimed invention as recited in claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57. Therefore, Applicants respectfully submit that Watanabe on its

own clearly fails to anticipate, either explicitly or inherently, or in the alternative, render obvious the claimed invention as defined in claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57.

Accordingly, Applicants respectfully request that the anticipation and obviousness rejections in view of Watanabe, on its own, be withdrawn.

In the Office Action, claims 1-72 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over Watanabe in view of U.S. Patent No. 4,630,727 ("Feriani") and van Bommel et al.. The Patent Office relies on Watanabe as its primary reference and thus relies on Feriani and van Bommel in further support of this rejection.

Applicants believe that the obviousness rejection in view of Watanabe, even if combinable with the other cited references, is clearly improper. As previously discussed, Watanabe on its own is clearly deficient with respect to claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57. Of the remaining pending claims, claims 30 and 64 are the sole independent claims and each recite, in part, that the first component and second component of the bicarbonate-based solution include a physiological acceptable amount of potassium in further contrast to Watanabe as even admitted by the Patent Office. Thus, on its own, Watanabe is clearly distinguishable from the claimed invention based on at least these reasons.

Further, Applicants do not believe that the Patent Office can rely solely on the remaining cited art to remedy the deficiencies of Watanabe. At the outset, the Patent Office even admits that the cited art and the claimed invention differ with respect to the claimed subject matter that recites a two part composition with potassium in both the bicarbonate part and the electrolyte part. See, Office Action, page 4.

Contrary to the Patent Office's further position, the cited art, even if combinable, fails to suggest such bicarbonate-based solutions and methods of use as claimed. Nowhere does the cited art provide motivation for potassium in both the bicarbonate and electrolyte parts that can be then mixed in a safe, effective and ready manner to provide a ready-to-use solution as defined in independent claims 30 and 64 and further defined in dependent claim 4 as supported in the specification. Indeed, the Watanabe and Feriani references provide that potassium can be an optional ingredient in the electrolyte part (See, Watanabe, col. 2, line 61) or in the bicarbonate part (See, Feriani, col. 6, lines 22-25). Moreover, the Patent Office merely relies on van Bommel et al. for its purported teaching that hemodialysis and continuous renal replacement therapy can use the same fluids. Thus, even if combinable, the cited art is distinguishable from a two part bicarbonate solution that includes an electrolyte and a bicarbonate part wherein each part

includes potassium in a physiological amount as defined in independent claims 30 and 64, such as potassium that ranges from about 0.1 mmol/L to about 5 mmol/L as further defined in claims 5 and 31.

Further, the cited art, even if combinable, is deficient with respect to the claimed invention for other reasons well. For example, nowhere does the cited art disclose or suggest two part solutions that include an electrolyte concentrate and a bicarbonate concentrate with sodium in a physiological amount as defined by independent claims 1 and 44, let alone in equimolar amounts, such as about 160 mmol/L, about 100 mmol/L or less as further defined by claims 2, 3, 19, 33, 45, 46, 57, and 66. The Watanabe reference is deficient with respect to the claimed sodium content features as discussed above. Feriani merely provides that sodium is present in the bicarbonate solution part. See, Feriani, col. 6, lines 22-24. Again, the Patent Office merely relies on van Bommel et al. for its purported teaching regarding hemodialysis and continuous renal replacement therapy. Indeed, dependent claims 4, 5, 19, 33, 57, and 66 recite bicarbonate-based solutions with a bicarbonate part and an electrolyte part that includes potassium (i.e., about 0.1 mmol/L to about 5 mmol/L) in at least the electrolyte part and sodium in equimolar or physiological amounts (i.e., about 160 mmol/L, about 100 mmol/L or less) in both parts. Clearly, the cited art fails to disclose or suggest bicarbonate-based solutions with such features that can be readily prepared for effective use as required by the claimed invention.

The cited art is also deficient with respect to the two part bicarbonate-based solutions that include an electrolyte part and a bicarbonate part with potassium in the electrolyte part as required by independent claims 17 and 55. Claim 17 further recites that the bicarbonate part and the electrolyte part are so constructed and arranged that the electrolyte part physically cannot be infused into the patient without mixing with the bicarbonate part. Claim 55 relates to a method of providing hemofiltration that further recites orienting the bicarbonate and electrolyte parts so that the electrolyte part physically cannot be infused into the patient without mixing with the bicarbonate part. This allows the bicarbonate and electrolyte parts to be readily mixed for effective use, such as during hemofiltration as claimed and discussed above.

In contrast, Watanabe is deficient with respect to bicarbonate-based solutions with such claimed features as discussed above. Indeed, Feriani effectively teaches away from such claimed features as it merely provides potassium as an optional ingredient in the bicarbonate part. Again, the Patent Office merely relies on van Bommel et al. for its purported teaching regarding hemodialysis and continuous renal replacement therapy. Moreover, dependent claims

5, 19 and 57 further require sodium in both the electrolyte and bicarbonate parts at equimolar or physiological amounts in addition to potassium in the electrolyte part. Clearly, the cited art is distinguishable from bicarbonate-based solutions with such claimed features that can provide the ready use of bicarbonate-based solutions in a safe and effective manner, such as applied to continuous renal replacement therapy including hemofiltration.

Based on at least these reasons and even if combinable, the cited art is distinguishable from the claimed invention. What the Patent Office has done is to rely on hindsight reconstruction to support the obviousness rejection. This is clearly improper. Indeed, the Patent Office relies on mere conclusions to support its position. See, for example, Office Action, page 4. Moreover, the cited art is deficient with respect to additional features as claimed and discussed above. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify the cited art to arrive at the claimed invention.

Based on at least these differences between the claimed invention and the cited art, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, alone or even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection of claims 1-72 in view of Watanabe and further in view of Feriani and van Bommel be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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Dated: April 29, 2004